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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,818	01/26/2004	Patricia A. Brown	AVSI-0033 (108328.00170)	8276
7590	02/09/2005			EXAMINER ABBOTT, YVONNE RENEE
T. Ling Chwang Jackson Walker L.L.P. #600 2435 North Central Expressway Richardson, TX 75080			ART UNIT 3644	PAPER NUMBER
DATE MAILED: 02/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
	BROWN ET AL.	
Examiner	Art Unit	
Yvonne R. Abbott	3644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 26 January 2004.  
2a) This action is FINAL.                    2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-99 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) 58-76 is/are allowed.  
6) Claim(s) 1-10,15,18,21-29,34,37,40-45,47,52,55,77-82,87-93,98 and 99 is/are rejected.  
7) Claim(s) 11-14,16,17,19,20,30-33,35,36,38,39,46,48-51,53,54,56,57,83-86 and 94-97 is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
    1. Certified copies of the priority documents have been received.  
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date 5/27/04.
- 4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 93 is objected to because of the following informalities: claim 93 is a duplicate of claim 92. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. Claims 5 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 5, "the electroporation method" lacks prior antecedent basis since it is recited in the alternative in the claim from which it depends.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 10, 15, 18, 21-24, 77, 78, 81, 82, 87-93, 98 and 99 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al. (6,423,693). Schwartz et al.

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discloses the identification and use of nucleic acid sequences which confer advantageous tissue targeting, expression, and secretion properties for encoding GHRH, and describes how GHRH enhances the immune system in animals, and is used to treat chronic diseases, improve healing and retard the aging process which thereby is considered to decrease cull and improve body condition; it is disclosed that injection of DNA vector which can comprise a transfection-facilitating polypeptide into the muscle, tissue, and cells of agricultural animals produces sustained levels of GHRH, and represents a practical method for improving performance in livestock animals; it is also disclosed that the vector may be delivered via an electroporation method; it is also disclosed that in farm animals, GHRH stimulates milk production.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2, 7-9, 26, 27, 28, 29, 34, 37, 40-45, 47, 52 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. ('693). That the mortality rate is decreased by 5% (from 20% to 15%) as recited in claim 2, or that the milk production is increased (from 8-18%) as recited in claim 45, is not specifically claimed, but since the general conditions are disclosed, through routine experimentation it would have been obvious to one skilled in the art to discover this range. With respect to claims 7, 8, 26, 27, 44, 47, and 58, although it is not specifically disclosed that the nucleic acid is delivered in a single dose, Schwartz et al. does disclose that the chosen method of delivery should result in expression of the gene product encoded within the nucleic acid cassette at levels which exert an appropriate biological effect, that the rate of expression will depend upon the disease, the pharmacokinetics of the vector and gene product, and the route of administration; and that this level is readily determinable by standard methods which could be more or less depending on the optimal dosing and efficacy data from clinical trials. Therefore, to concluded that delivery of only a single dose produces the desired effect (be it reducing disease or improving milk yield) would have been obvious since where routing testing and general experimental conditions are present, discovering the optimum or workable ranges until the desired effect is achieved involves only routing skill in the art. Claims 9 and 28 recite subject matter dependent upon the type of animal on which the procedure is performed (i.e. the animal would have to be one whose cells are diploid in nature), thus it would be obvious to one skilled in the art performing the procedure disclosed by

Schwartz et al. that the delivery into tissue comprised of cells would include diploid cells in an animal comprised of such.

7. Claims 3-5, 79, 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. ('693) in view of Schwartz et al. (US 2003/0074679) which discloses the administration of nucleic acid sequence such as GHRH to animals, preferably through a parenteral route to enhance growth of offspring.

***Allowable Subject Matter***

8. Claims 58-76 are allowed.

9. Claims 11-14, 16, 17, 19, 20, 30-33, 35, 36, 38, 39, 46, 48-51, 53, 54, 56, 57, 83-86, and 94-97 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

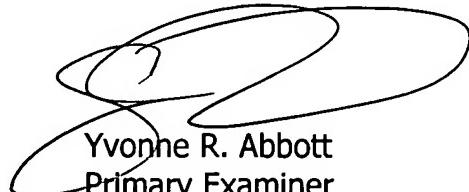
10. Claims 6 and 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne R. Abbott whose telephone number is (703)308-2866. The examiner can normally be reached on Mon-Thurs 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Teri Luu can be reached on (703)305-7421. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Yvonne R. Abbott  
Primary Examiner  
Art Unit 3644

2/7/05